The following corrections or additions to the January 2004 list were published in the Federal Register in September 2004.

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 128-409

This supplemental application provides for the extension of the period of persistent effect for *Oesophagostomum radiatum* from 14 days to 28 days and for *Trichostrongylus axei* and *Cooperia punctata* from 14 days to 21 days in cattle; and a veal calf warning statement has been added.

Trade Name: Ivomec® Injection for Cattle and Swine
Ingredients: Ivermectin
Sponsor: Merial Ltd.
Approval Date: August 16, 2004
Species: Cattle, excluding veal calves.
Exclusivity: 3 years

21CFR 522.1192

NADA Number: 140-439

This supplemental application provides for revised labeling including the addition of four new species of internal parasites (*Craterostomum acuticaudatum, Petrovinema poculatum,* and *Coronocyclus* spp, including *Coronocyclus coronatus* and *Coronocyclus labratus*).

Trade Name: Eqvalan® Liquid for Horses
Ingredients: Ivermectin
Sponsor: Merial Ltd.
Approval Date: August 9, 2004
Exclusivity: 3 years

21CFR 520.1195

NADA Number: 141-215

This supplemental application provides for use in breeding, pregnant, or lactating mares without adverse effects on fertility.

Trade Name: Equimax™ Paste
Ingredients: Ivermectin, praziquantel
Sponsor: Virbac, AH Inc.
Approval Date: July 30, 2004
Exclusivity: 3 years

Actions Taken by FDA Center for Veterinary Medicine

ANADA Number: 200-061

This supplemental application provides for the addition claim of control of fever and inflammation for intravenous use in beef cattle and non-lactating dairy cattle.

Trade Name:	Flunixin Meglumine Solution
Ingredients:	Flunixin meglumine
Sponsor:	Agri Laboratories, Ltd.
Approval Date:	July 29, 2004
Indications:	For the control of pyrexia associated with bovine respiratory disease and endotoxemia, and for the control of inflammation caused by endotoxemia.
Tolerance:	21 CFR 556.286 Flunixin meglumine: For residues of parent flunixin free acid of 0.125 part per million in cattle liver (target tissue) and 0.025 part per million in cattle muscle are established.
Withdrawal:	4 days - cattle

21CFR 522.970

Suitability Petition Action

Number:	04P-0376/CP1
Sponsor:	Bioniche Animal Health USA, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug progesterone which differs from the pioneer product, EAZI-Breed™ CIDR® Cattle Insert, Pharmacia & Upjohn Co., NADA 141-200 by the following characteristic(s): The generic product will have a change in strength (concentration) from the pioneer.
Action:	Filed on August 24, 2004.

Number:	04P-0383
Sponsor:	Anacare New Zealand Ltd.
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Ivomec® Pour-On for Cattle, Merial Ltd., NADA 140-841 by the following characteristic(s): The generic product will have a change in strength (concentration) from the pioneer.
Action:	Filed on August 31, 2004.

Number:	04P-0384
Sponsor:	Anacare New Zealand Ltd.
Petition:	Request permission to file an ANADA for a generic new animal drug levamisole hydrochloride which differs from the pioneer product, Levasole® Soluble Drench Powder, Schering-Plough Animal Health Corp., NADA 112-051 by the following characteristic(s): The generic product will have a change in strength (concentration) and dosage form from the pioneer.
Action:	Filed on August 31, 2004.

Correction of a Final Rule

The Food and Drug Administration (FDA) is correcting a document amending the animal drug regulations to reflect approval of an original abbreviated new animal drug application (ANADA) that appeared in the Federal Register of August 18, 2004 (69 FR 51172) (Green Book update of September 2004). FDA is removing the drug labeler code for Pennfield Oil Co. in the entry for use of single-ingredient bacitracin methylene disalicylate (BMD) in swine feed, which was added in error during document formatting; and is adding the approved source of BMD in the entry for use of BMD in combination with chlortetracycline. These corrections are being made so the BMD regulations accurately reflect approved new animal drug applications. This rule is effective September 27, 2004.

Notice(s)

Guidance For Industry: "Animal Drug Sponsor Fees Under the Animal Drug User Fee Act (ADUFA)"
The Food and Drug Administration (FDA) is announcing the availability of a draft guidance #173 entitled ``Guidance For Industry: Animal Drug Sponsor Fees Under the Animal Drug User Fee Act (ADUFA)." This draft guidance describes how FDA intends to implement the Federal Food, Drug, and Cosmetic Act (the act) as it relates to animal drug sponsor fees.
Submit written or electronic comments on the draft guidance by October 28, 2004, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time. Written requests for single copies of the draft guidance document should be directed to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Include one self-addressed adhesive label to assist that office in processing your requests. Comments should be identified with the full title of draft guidance #173 and the docket number (2004D-0422).
Submit written comments on the draft guidance document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit comments electronically via the Internet at http://www.fda.gov/dockets/ecomments docket number 2004D-0422. For further information contact: David Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: dnewkirk@cvm.fda.gov.

Guidance for Industry "Use of Material from BSE-Positive Cattle in Animal Feed"
The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry #174 entitled ``Use of Material from BSE-Positive Cattle in Animal Feed." This guidance document describes FDA's current thinking regarding the use in all animal feed of all material from cattle that test positive for BSE (bovine spongiform encephalopathy). Submit written or electronic comments on agency guidance at any time. Written comments should be directed to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance via the Internet at http://www.fda.gov/dockets/ecomments identified with the docket number (2004D-0438).
Single copies of the guidance can be obtained from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. For further information contact: Burt Pritchett, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6860, e-mail: burt.pritchett@fda.gov.